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**Response to Restriction Requirement and Request for Reconsideration**

According to the restriction requirement, claim 1 is a linking claim that "links inventions consisting of Groups I through XLIII wherein each group consists of claims 1-55 drawn to a patentably distinct promoter sequence selected from the group consisting of SEQ ID NOS: 1-43" (Office Action, page 2).

*Traversal of Restriction Requirement*

Applicants respectfully traverse the restriction requirement on at least two grounds. First, the restriction requirement does not follow the procedure set forth in 37 CFR §§ 1.141-1.146 and the corresponding sections of the MPEP for handling generic claims. According to 37 CFR § 1.141, an applicant may not claim two or more independent and distinct inventions in a single application "except that more than one species of an invention . . . may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim." (emphasis added). Thus, "[w]here an application contains a generic claim for all of the disclosed species, a restriction usually is not proper." *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F. Supp. 1397, 1436, n. 16, n. 17 (N.D. Ill. 1996).

The procedure for handling applications that include generic claims is set forth in 37 CFR § 1.146. This rule provides that "[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable." As stated in MPEP § 809.02(a), "[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141." Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable.

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In the instant case, the required procedure is not being followed. Claims 1, 56, 63, 64, 67, 71, 74 are each proper generic claims within the requirements set forth in 37 CFR § 1.141. These claims satisfy the definition of a generic claim as set forth in MPEP § 806.04(d), in that none of these generic claims includes limitations that are not present in all claims that depend from the respective generic claims. Therefore, an election of species requirement is permissible, but a restriction requirement is not.

Moreover, because the restriction requirement splits a single claim into multiple groups (claim 1, for example, is split into 43 groups), the restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, i.e., 35 U.S.C. 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions. See, *In re Weber*, 198 USPQ 328, 331 (CCPA 1978); *In re Haas*, 179 USPQ 623, 624-625 (*In re Haas I*) (CCPA 1973) and *In re Haas* 198 USPQ 334-337 (*In re Haas II*) (CCPA 1978). As stated in *In re Weber*:

"The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it." 198 USPQ 328 at 334.

In a case such as the instant case, where a claim is generic, a restriction requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in *In re Haas I*:

"We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained." 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will never be accorded "the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ at 331. In *In re Weber*, the CCPA stated that "[a]s a general proposition, an applicant has

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a right to have *each* claim examined on the merits" (198 USPQ at 331, emphasis in original).

The Court went on to state that:

"If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification." 198 USPQ at 331.

Even if Applicants were to file 42 divisional applications to obtain coverage for each of the promoters specified in the claims in each group as set forth in the restriction requirement, they would not have the opportunity to have their broader claims examined. The claims of the divisional applications would be limited to the particular species set forth in the respective groups. One seeking to avoid infringement could simply choose a protein solubility responsive promoter that is not specifically disclosed in the application. In effect, the restriction requirement is reading into Applicants' independent claims limitations that are not present in the claims as filed. Claim 1, for example, would never be considered under the current restriction requirement. Only the dependent claims which are set forth in the respective groups would be examined.

Applicants therefore respectfully request that the instant restriction requirement be withdrawn and treated as though it were a species election under the procedure set forth in MPEP 809.02(a). Pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the restriction requirement at any time prior to appeal. Applicants also note that because the instant rejection is tantamount to a rejection of the generic claims, the restriction requirement is appealable to the Board of Patent Appeals and Interferences. *In re Haas I*.

Applicants further note that the restriction requirement does not refer at all to claims 56-76. Accordingly, Applicants presume that these claims will be examined in the instant case.

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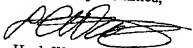
*Election*

Subject to the traversal set forth above, Applicants hereby elect the *ibpA* promoter (SEQ ID NO:21 and also SEQ ID NO:23). Claims that are readable upon this species are claims 1-72.

CONCLUSION

In view of the foregoing, Applicant believes that this application is now in condition for examination. If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1547.

Respectfully submitted,



Hugh Wang  
Reg. No. 47,163

For

Timothy L. Smith, Ph.D.  
Reg. No. 35,367

GENOMICS INSTITUTE OF THE NOVARTIS RESEARCH FOUNDATION  
10675 John Jay Hopkins Drive, Suite E225  
San Diego, CA 92121  
Tel: (858) 812-1547  
Fax: (858) 812-1981